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1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

- 2. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 - 1. Determining the scope and contents of the prior art.
 - 2. Ascertaining the differences between the prior art and the claims at issue.
 - 3. Resolving the level of ordinary skill in the pertinent art.
 - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 3. Claims 1-11, 13-23, 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Karp I (2003/0223913) in view of Karp II (2003/0159742) and Ramsey (5858195).
- 4. Karp I teaches providing a microfluidic device having entry ports 81, 83, 85, column 82 and reservoir 94 (Fig. 4). The purification material is loaded into the column using a slurry, the column is then wetted with a solvent, and a sample is loaded, eluted and passed to a waste reservoir. The material can include size exclusion or ion exchange material. Mobile phases are moved by pressure, such as gravity, pumping or electric field. The sample can be biological. See, e.g., [0003-0005], [0043], [0050], [0053], [0055]. With respect to another embodiment, the slurry packing method is described as providing particulate material in an excess of solvent, retaining the particulate in the column and removing the excess solvent [0060].

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5. Karp I fails to explicitly teach passing both the excess solvent and the eluted sample into the waste reservoir or the waste reservoir in the substrate.

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- 6. Karp II teaches a device and method similar to that of Karp I. Both excess solvent form the slurry and the eluted sample are passed form the device using the same channel ([0042]).
- 7. Ramsey teaches a device similar to that of Karp I and Karp II, including chromatography column 34A and waste reservoir 20A (Figure 3). The waste reservoir is provided in the device substrate (Figure 6).
- 8. It would have been obvious to one of ordinary skill to pass the excess solvent from the slurry loading process and the eluted sample Karp I into the waste reservoir of the embodiment of Figure 4 in order to pass the solvent and sample form the device using the same channel as taught by Karp II. It would have been obvious to provide the waste reservoir in the device substrate as taught by Ramsey in order to provide a self-contained device. It is the examiner's position that the solvent and sample would inherently mix in the reservoir. With respect to claims 3-5, 7-9, it would have been obvious to use any known pumping force in order to generate the pressure required to move the fluids. With respect to claims 19-21, it would have been obvious to provide known sample preparation and analytical techniques prior to or subsequent to separation.
- 9. Applicant's arguments with respect to claims 1-11, 13-23, 34 have been considered but are moot in view of the new ground(s) of rejection.

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10. The examiner notes that applicant argues that Karp I teaches that the stationary phase material is fully wetted, whereas in the instant claims, the purification material is free of excess diluent. However, in the instant claims, the purification material is saturated with diluent. How is "saturated" different from "fully wetted"? Note that the examiner is defining "excess diluent" as the diluent in the packing slurry, which excess is removed during the packing process, leaving the fully wetted (saturated) stationary phase in the column. It is the examiner's position that the combination of Karp I and Karp II suggests that this excess diluent is passed to waste and it would have been obvious to collect waste in a waste reservoir, and that after passage of the sample through the column and detection, the sample is similarly passed to the waste reservoir, resulting in the instantly claimed method. Note that while the prior art may not intend to produce a diluted sample, the combination does suggest passing both excess slurry diluent and sample to waste and for waste to be collected in a waste reservoir, resulting in the claimed steps, regardless of why these steps are performed. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See Ex parte Obiaya, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). 11. Applicant's amendment necessitated the new ground(s) of rejection presented in

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11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jan M. Ludlow whose telephone number is (571) 272-1260. The examiner can normally be reached on Monday, Tuesday and Thursday, 11:30 am - 8:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jan M. Ludlow Primary Examiner Art Unit 1797

/Jan M. Ludlow/ Primary Examiner, Art Unit 1797